

**REMARKS**

Reconsideration of this application is respectfully requested.

The listing of claims amends claims 17, 18, and 22, and adds new claims 36 and 37. Claims 17, 18,, 21-23, and 34-37 are pending.

New claims 36 and 37 are supported by claim 22 as originally filed and do not add new matter. The amendment to replace the term "SP13" with the term "SPI3" merely corrects a typographical error that is apparent from the specification on page 10, line 18. In addition, the amendments to claims 17 and 18 are supported by the specification on page 20, lines 6-11, and the amendments to claim 22 are supported by the paragraph bridging pages 10 and 11 of the specification. No new matter is added by these amendments.

**35 U.S.C. § 112**

In item 2 of the Office Action mailed December 29, 2005, the Office rejected claim 22 as being indefinite under 35 U.S.C. § 112, second paragraph, because it asserted that the terms "SMN,", "NT-3," "NT-4/5," "CRE," and "ICE" are vague. Without altering the scope of claim 22, Applicants have included the full length names "Survival Motor Neuron" for "SMN," "Neurotrophin-3" for "NT-3," "Neurotrophin 4/5" for "NT-4/5," and "Interleukin -1 Converting Enzyme" for "ICE."

In regard to the term "CRE," Applicants note that this term, as well as the term Scel, have been deleted from claim 22 and provided in a new claim 36. In response to the rejection, a more complete name for "CRE" is not discernable from the literature cited. Nevertheless, the term is not vague because it is defined in the specification as an "endonuclease . . . or CRE (Gu, H. et al. (1994), Science **265**:103-106); . . . ."

Specification at page 11, lines 1-3. Thus, one of skill in the art would be able to determine the identity of "CRE" from the cited reference.

Because none of the terms recited from claim 22 by the Office are vague, Applicants respectfully request that the rejection be withdrawn.

35 U.S.C. § 102

In item 4, the Office rejected claims 17 and 21 as being anticipated by Fairweather (U.S. Patent No. 5,443,996) under 35 U.S.C. § 102. The Office asserted that Fairweather teaches a polypeptide that comprises 121 residues of B fragment and all 451 carboxy-terminal residues of the C fragment of tetanus toxin, in anticipation of the invention of claim 17. Furthermore, the Office asserted that Fairweather teaches a solution containing the expressed hybrid protein, which the Office considered to be an "active molecule," in anticipation of claim 21.

In response, Applicants note that Claim 17, and thus claim 21, which depends from claim 17, recite "a fragment C and a fraction of fragment B having 11 amino acid residues (amino acids 854-1315 of the tetanus toxin holotoxin)." Fairweather does not teach a polypeptide of amino acids 854-1315 of the tetanus toxin holotoxin and so cannot anticipate the claimed invention.

In item 5, the Office also rejected claims 17 and 22 as being anticipated by Fishman (Society for Neuroscience Abstracts (1996) vol. 22, pp. 1705). The Office asserted that Fishman teaches the full-length tetanus toxin. Fishman does not teach "a fragment C and a fraction of fragment B having 11 amino acid residues (amino acids 854-1315 of the tetanus toxin holotoxin)," though. Therefore, Fishman cannot anticipate the invention of claim 17 or the embodiment claimed in claim 22.

Because neither Fairweather nor Fishman anticipates the claimed invention, Applicants respectfully request that the rejections under 35 U.S.C. § 102 be withdrawn.

35 U.S.C. § 103

In item 8, the Office rejected claims 17, 18, 21, 23, 34, and 35 as being obvious under 35 U.S.C. § 103 in light of Fishman, Mueller (Report, ARO-27890.1-LS Order No. AD-A290 501, NTIS, p. 1-15) and Hühne-Zell (FEBS Letters (1993) vol. 336, p. 175-80). In brief, the Office asserted that Fishman teaches full-length tetanus toxin, while Mueller teaches the use of fragment C for uptake by neurons and Hühne-Zell teaches abolition of the activity of the light chain by replacing amino acids of the zinc binding domain.

Neither Fishman, Mueller, nor Hühne-Zell teach or suggest a “hybrid fragment of tetanus toxin comprising a fragment C and a fraction of fragment B having 11 amino acid residues (amino acids 854-1315 of the tetanus toxin holotoxin),” as recited in independent claims 17 and 18. Furthermore, one of skill in the art would not be motivated from the combination of these references to develop the claimed invention. Because claims 17 and 18, and claims 21, 23, 34, and 35, which depend from them, provide for this element, the cited references do not render the claimed invention obvious.

In item 9 the Office found claims 17, 21, and 22 to be obvious in light of Fishman, Mueller, and Khan (WO 95/04151) because it asserted that Fishman teaches the full-length tetanus toxin, Khan teaches a fusion protein between the C fragment of tetanus toxin and a heterozygous protein as a vaccine, and Mueller teaches using the C fragment for uptake into neurons. But, none of these references teaches or suggests a “hybrid fragment of tetanus toxin comprising a fragment C and a fraction of fragment B

having 11 amino acid residues (amino acids 854-1315 of the tetanus toxin holotoxin)."

Furthermore, one of skill in the art would not be motivated from the combination of these references to develop the claimed invention. Because neither claim 17, nor claims 21 and 22, which depend from them, recite this element, the cited references do not render the claimed invention obvious.

Applicants respectfully request that the rejections under 35 U.S.C. § 103 be withdrawn.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: June 28, 2006

By:  Salvatore J. Arrijo  
For: Deborah Katz Reg. No. 46,063  
Reg. No. 51,863  
Phone: 202.408.4382  
Fax: 202.408.4400  
E-mail: deborah.katz@finnegan.com